



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 24, 2017

Ms. Cynthia Ann Smith
U.S. Agent
Kaken Pharmaceutical Co. Ltd.
c/o Conn & Smith Inc.
6713 Catskill Road
Lorton, VA 22079

Subject: Pesticide Registration Improvement Act (PRIA) Formulation and Label Amendment –
PRIA B681: Amendment to the Manufacturing Process Resulting in Minor Amendment
to the CSF Reflecting New Impurity Profile and a New Label Reflecting a New Est.#.
Product Name: Polyoxin D Zinc Salt Technical
EPA Registration Number: 68173-1
Application Date: 7/25/2016
OPP Decision Number: 520035

Dear Ms. Smith:

The amended Manufacturing Process, labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 7/25/2016

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be

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considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Chris Pfeifer of my team by phone at 703-308-0031 or via email at pfeifer.chris@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew C. Bryceland". The signature is written in a cursive style with a large, sweeping flourish at the end.

Andrew C. Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs

ACCEPTED
03/24/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 68173-1

Polyoxin D Zinc Salt Technical
For Manufacturing Use Only

GROUP 19 FUNGICIDE

| | |
|---|---------------|
| Active Ingredient: | |
| Polyoxin D zinc salt (1:1) ¹ , | |
| Zinc 5-[[2-amino-5- <i>O</i> -(aminocarbonyl)-2-deoxy-L-xyloonyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2 <i>H</i>)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate | 23.8% |
| Other Ingredients: | 76.2% |
| Total: | 100.0% |

¹ Equivalent to 21.1% polyoxin D and 2.65% metallic zinc.

KEEP OUT OF REACH OF CHILDREN
CAUTION

| FIRST AID | |
|---|--|
| If on skin or clothing | <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice. |
| If in eyes | <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice. |
| If swallowed | <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything by mouth to an unconscious person. |
| If inhaled | <ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice. |
| HOTLINE NUMBER | |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE: Call CHEMTREC at 1-800-424-9300 or POISON CONTROL CENTER at 1-800-222-1222 or 1-703-527-3887 if calling from outside of the U.S. | |

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Harmful if absorbed through the skin, swallowed or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

This pesticide is moderately toxic to aquatic invertebrates and fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant

authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Polyoxin D Zinc Salt Technical is for manufacturing use only for the production of fungicide formulations for use on all food and feed crops (pre-harvest and post-harvest), ornamentals, golf courses, residential lawns, parks, and commercial and institutional grounds.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in dry place away from food or feed.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into manufacturing equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

FOR 24-HOUR CHEMICAL EMERGENCY ASSISTANCE:

(Spill, leak, fire, exposure or accident), call CHEMTREC 1-800-424-9300
or 1-703-527-3887 if calling from outside of the U.S.

WARRANTY AND DISCLAIMER STATEMENT

1. Kaken Pharmaceutical Co., Ltd. ("Kaken") warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks described above, when used in accordance with the Directions for Use under normal conditions.
2. This warranty does not extend to the use of this product contrary to label instructions or under conditions not reasonably foreseeable to Kaken, and is subject to the inherent risks described above. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, KAKEN DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, KAKEN, MANUFACTURER, AND SELLER DISCLAIM AND SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE, HANDLING, APPLICATION, STORAGE OR DISPOSAL OF THIS PRODUCT OR FOR DAMAGES IN THE NATURE OF PENALTIES, AND THE USER AND BUYER WAIVE ANY RIGHT THAT THEY MAY HAVE TO SUCH DAMAGES. NO AGENT, REPRESENTATIVE OR EMPLOYEE OF KAKEN IS AUTHORIZED TO MAKE ANY WARRANTY, GUARANTEE OR REPRESENTATION BEYOND THOSE CONTAINED HEREIN OR TO MODIFY THE WARRANTIES CONTAINED HEREIN.**
3. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE TOTAL LIABILITY OF KAKEN, MANUFACTURER, AND SELLER, SHALL BE LIMITED TO THE PURCHASE PRICE PAID, OR AT KAKEN'S ELECTION, THE REPLACEMENT OF THE PRODUCT.**

EPA Reg. No: 68173-1
EPA Est. No: 68173-JP-001 (or 70552-TWN-1)

Net Contents:

Produced by:
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